MINUTES OF THE MEETNG

TERTIARY CARE ADVISORY COMMITTEE

DATE: 26 February 2008 TIME: 1:00 PM

LOCATION: Conference Room 401

Department of Health, Cannon Building

ATTENDENCE:

Council: Present: Gregory Allen, DO, John Flynn, Catherine Graziano, RN, PhD, Joan Kwiatkowski, Robert J. Quigley, DC, (Chair)

Excused Absences: Sam Havens, Robert S.L. Kinder, MD, Gus Mannocchia, Ed Quinlan

Staff: Valentina Adamova, Loreen Angell, Jay Buechner, Michael K. Dexter

Public: (Attached)

1. Call to Order, Approval of Minutes, Conflict of Interest Forms and Time Extension for the Minutes Availability

The meeting was called to order at 1:10 PM. The Chairman noted that conflict of interest forms were available to any member who may have a conflict. Minutes of the 29 January 2008 meeting were approved as submitted. The Chairman requested a motion for the extension of time for the availability of minutes pursuant to the Open Meetings Act. A motion was made, seconded and passed by a vote of five in favor and none opposed (5-0) that the availability of the minutes for this meeting be extended beyond the time frame provided for under the Open Meetings Act. Those members voting in favor were: Allen, Flynn, Graziano, Kwiatkowski, Quigley.

2. General Order of Business

The main item on the agenda was the discussion of standards for primary and elective angioplasty. Staff noted that four issues relating to angioplasty were before the committee for review: minimum volume requirement for an angioplasty program; if primary angioplasty were permitted at a facility without onsite cardiac backup surgery and, if so, what the requirements should be for the program; and if a minimum volume for operators should be required in regulation. Staff noted the minimum volume for an angioplasty program was reviewed by the committee in 2004 over a series of ten meetings in which it was determined the minimum requirement would be maintained at 400.

A chart detailing the number of angioplasties performed per physician for fiscal year 2006 was distributed and staff stated an attempt to update with 2007 data would be made. Staff stated that with regard to whether or not a minimum volume for operators should be required in regulation, the committee has heard that 75 per operator has been the recommended amount; 11 for primary angioplasty. The Chairman stated angioplasties performed out of state would not be reflected on the physician volume chart. Arthur Klein, MD, Senior Vice President and Chief Physician Officer of Lifespan stated that Kenneth Korr of Landmark was privileged at Charlton at the time of the data, but that he would probably not be seeking to be re-privileged for angioplasties.

Joan Kwiatkowski inquired if the physician volume data was reviewed by Harvey Zimmerman for potential overlap, as previous hospital admission data reflected inflation. Mr. Zimmerman stated hospital admission volumes may reflect inflation due to transfer, but procedures were accounted for per physician, eliminating duplication.

John Flynn stated that if the previous committee studied the issue of angioplasty volume to the extent noted, and established 400 as a minimum number for angioplasty procedures, he wouldn't be inclined to reduce the number unless a good reason were provided. The Chairman explained it was the first time the committee looked at the issue and as it was examined, information continued to come in,

which contributed to the number of meetings that were set for the issue.

Gregory Allen noted that the minimum number of 75 angioplasties per physician was backed up by AHA recommendations, but inquired of Mr. Zimmerman if the minimum volume requirement of 400 procedures annually for an angioplasty program was backed up by data. Mr. Zimmerman stated that 400 had been confirmed by several recent studies. He noted that a study which recommended 200 as a minimum for angioplasty programs, was weak due to lack of good measurements of confounding variables that would affect the outcome, as well as the fact that the study looked only at mortality and not other adverse effects. Mr. Zimmerman noted that the study is not regarded in high esteem as other studies such as New York studies that continue to find 400 gives the greatest relative benefit between low volume and high volume hospitals.

Staff clarified an earlier comment, stating the committee looked at primary angioplasty without onsite cardiac backup surgery in 2004, but did not formally revisit the minimum number of 400 procedures required by a facility with an angioplasty program that was set in 2000.

Senator Graziano stated it was identified that numbers were going down due to lower risk factors and better treatment. Therefore if the minimum requirement remained 400 and PCI use continued to

decrease, the number of facilities able to perform angioplasties would be limited.

Mr. Zimmerman noted that PCI use in Rhode Island is currently distributed between three hospitals as 2007 data shows: Rhode Island Hospital (951), Miriam (1,566) and Landmark (358). He stated the only hospital that would be affected by the minimum requirement would be Landmark, but did not anticipate that as their numbers were still increasing.

Staff reinforced that the minimum volume requirement had to be considered in light of peer- reviewed literature or other accrediting agencies and not based on volumes within the state.

Senator Graziano noted that Landmark is ramping up but inquired what action would be taken if the minimum volume of 400 were not met. Staff stated that regulations provide for a plan of correction, such as how quality could be assured if the numbers were not met. Michael Coady, MD of Landmark stated that 2008 numbers were increasing and difficulty was not anticipated in meeting the 400.

Gregory Allen stated some of the volume seen at the three hospitals currently performing angioplasties is generated from Kent Hospital, which has an application before the council. He stated an additional decrease in angioplasties at the current hospitals would be realized as Kent came on board. Staff stated that if a new provider were to be

authorized to perform angioplasties, a Certificate of Need would have to be granted which would involve a review of the impact of the proposed service on other providers providing similar services. Staff additionally stated that the Kent application is limited to primary angioplasties, in which 60 are proposed the first year.

The Chair asked Dr. Coady if Landmark physicians performed angioplasties at any Massachusetts hospitals that would not have been captured in Rhode Island physician volume data. Dr. Coady stated they did not.

A report regarding institutional volumes for PCI with off-site cardiac surgery backup as well as a data set detailing the association between hospital volume and mortality was distributed to the committee per John R. Audett, MD, Senior Vice President for Medical Affairs for Kent. Dr. Audett summarized the report, pointing out that two states (West Virginia and California) are in the process of establishing regulations to allow elective PCI in hospitals that have off-site cardiac surgery backup with institutional volumes of 200 PCIs per year. Dr. Audett stated 200 was recommended as an institutional volume, citing a recent study and the SCAI Expert Consensus Document. Additionally, Dr. Audett referenced a report from the ACC/NCDR database in which little difference was found in the in-hospital mortality rate for ST-Elevation MI between low and high volume hospitals. He noted a trend favored high volume hospitals for elective PCI but the difference was not large enough to be statistically

significant.

Mr. Zimmerman inquired how many hospitals and data years were included in the data set distributed by Dr. Audett. Dr. Audett stated the information included the entire database from the ACC (American College of Cardiology) for 2007. Mr. Zimmerman commented on the data, stating the ACC was voluntary and the hospitals that belong are generally good hospitals so the positive data was not surprising given the caliber of the participants.

Staff inquired if Dr. Audett was suggesting an institutional volume of 200 for PCI with or without surgical backup on site. Dr. Audett affirmed.

Joan Kwiatkowski inquired why the volume shifted from 400 to 200 and was not more of a median shift to the 300 range. She additionally questioned if other states have different standards or other professional organizations encourage a number above 200.

Mr. Zimmerman pointed out the volume groupings from the ACC data were based on the volume from hospitals in the database and were created to allow statistical tests on the data. He noted that traditionally, 200, 400 and 600 are the numbers assessed because these are the points at which the data breaks and if differences exist they are seen at these markers.

Staff inquired if Mr. Zimmerman was aware of a volume threshold for Massachusetts. Mr. Zimmerman noted that the information was not known. Dr. Audett referred to the report of Institutional Volumes for PCI with Off-Site Cardiac Surgery Backup, noting six states, including Massachusetts, allow elective PCI at non-surgical hospitals by regulation, pilot study or demonstration project without any minimum volume criteria.

John Flynn stated that if lowering the volume for angioplasty were considered that it could not be done without simultaneously reviewing the volume for operators. Additionally, Mr. Flynn inquired if there was any data showing how many patients are transferred to sites that have backup cardiac surgery. Mr. Zimmerman stated he looked at that in his last presentation but did not have data with him. Robert Baute, MD, former President and CEO of Kent, stated that data exists but the numbers are very small – approximately .5%.

Ms. Kwiatkowski expressed it was difficult to assess the consequence or impact of a steep drop from 400 to 200 in terms of economic sustainability or access to care. She noted the states referenced by Dr. Audett that have either a lower or no threshold were rural or large states and those thresholds provided access to care. Ms. Kwiatkowski stated Rhode Island is neither rural nor large so it would not be beneficial to use those states as a comparison. She voiced her support for the strategy behind the assessment of the minimum volume, however, as 400 seemed artificial.

Staff noted Mr. Zimmerman recently reviewed literature and provided reports to the committee which recommended the standard remain at 400. Staff noted if Dr. Audett were suggesting new information was available that was not considered in these reports, Mr. Zimmerman would review it to ensure the requirements set forth in the statute were met: volume to quality as demonstrated in peer reviewed health and medical literature or accrediting standards that are in place.

Mr. Allen inquired if the 2004 ACC/AHA guidelines had changed. Mr. Zimmerman noted guidelines generally take three years to update, but the ACC/AHA had been providing focused updates on components within the guidelines that had changed. He stated those updates did not address volume, so by implication the volume recommendation was maintained at 400.

Ms. Kwiatkowski suggested the committee review Landmark's numbers during their ramp up period in which they were below the 400 mark to serve as a reference point for the committee in terms of performance below the recommended volume of 400. Dr. Coady of Landmark noted volume is being explored as a surrogate for outcome and cautioned that both institutional and physician volume need to be considered as some physicians perform procedures across multiple institutions.

Dr. Klein suggested conflicting data exists regarding projected

angioplasty volume. He noted 2007 was a bad year in terms of volume due to national attention paid to the negative effects of drug-eluting stents. He stated new technology would emerge in upcoming years and he was not convinced that the 10% volume decrease would continue. Mr. Zimmerman noted this is supported in literature.

Ms. Kwiatkowski stated the number of angioplasties performed in the state has remained relatively stable over the years, fluctuating by 200. She noted if the institutional volume requirements were lowered the pool would be spread across a greater number of hospitals, causing economic impact.

Dr. Audett reiterated the SCAI guidelines suggested a 200 minimum volume threshold and provided a copy to the committee to be distributed to members in advance of the next meeting. Staff cautioned members to review all data set forth and not focus only on certain components.

The second issue to be reviewed was if primary angioplasty should be permitted at a hospital without onsite backup cardiac surgery services. Mr. Zimmerman stated there is no literature to demonstrate having backup cardiac surgery services for elective angioplasty has a lifesaving effect, but that is more of a quality of life issue. He stated a mortality benefit is realized when backup cardiac surgery services are present for primary angioplasty. For that reason, Mr. Zimmerman

stated, the requirement of onsite cardiac surgery for primary PCI programs was relaxed, but the ACC/AHA still recommends elective programs have backup surgery. Mr. Zimmerman stated the PRAGUE-2 study found approximately 4 patients of 1,000 required immediate cardiac surgery after primary PCI; another review of six studies which included over 1500 patients realized similar results. He stated these numbers favorably compared with the reduction in mortality received from immediate PCI relative to a patient transfer (4 per 1,000).

The Chair inquired if the requirement were relaxed whether or not a transport program standard would be required. Mr. Zimmerman affirmed, noting it was a Class 1 recommendation that an institution performing primary PCI without on-site cardiac surgery have a written protocol for transferring those patients. It was noted that written guidelines exist from the ACC/AHA guidelines.

The Chair asked what the consensus of the committee was regarding the issue. Mr. Flynn recommended that the requirement be relaxed to permit the provision of primary angioplasty without on-site cardiac backup surgery when a written transport protocol exists. The committee agreed with the recommendation which addressed issues two and three before the committee. Dr. Audett suggested the list of ACC/AHA guidelines be considered when defining the protocol as structure and necessary resources to implement such a protocol were clearly laid forth.

Staff noted the final issue before the committee, whether or not a minimum volume for operators should be set, was encountered 8 – 10 years ago when the committee was looking at setting facility volume requirements. At that time the committee did not recommend setting individual volume requirements per physicians. Staff inquired if Mr. Zimmerman had any comments.

Mr. Zimmerman stated an institutional volume-to-outcome relationship generally exists but the operational volume-to-outcome relationship varies. He stated studies suggest the difference is explained by institutional volume and not the physician volume, pointing to the impact of the team on operator results. Mr. Zimmerman noted a difference exists when looking at primary angioplasty for individual operators. A New York study demonstrated Primary PCI operators that did more than 10 per year had a significantly better outcome than those doing less. Therefore the recommendations of the ACC/AHA state a physician performing primary angioplasties must perform 75 total angioplasties and 11 primary angioplasties per year. He noted 75 is a softer number and 11 a harder number.

Staff inquired if an operator volume requirement were set if a separate volume requirement had to be set for those operators to perform a minimum number of primary angioplasties. Mr. Zimmerman replied that the minimum number of primary

angioplasties should be set only for those physicians performing primary angioplasties as recommendations clearly specify primary and elective PCI are not the same procedure and should not be subject to the same criteria.

Staff noted if the standards developed for primary angioplasty did not require onsite surgery, the 11 primary angioplasties could be built into the base requirement if the committee did not want to commit to the larger requirement of 75, as it was not a firm number. Mr. Zimmerman stated there are mixed results regarding 75 as some studies support it and some do not find a significant relationship. Dr. Audett, referencing the SCAI ACC/AHA guideline, which recommends 75 angioplasties and 11 primary angioplasties, suggested the committee should implement the numbers based on an identified guideline until further data is released.

Ms. Kwiatkowski stated she was supportive of establishing a minimum of 75/11 as it seemed consistent with all the data the committee had seen, but suggested language be included stating if the number was below 75, a mentor relationship or qualifying plan as to why the individual was practicing less be identified. She indicated the individual could be retiring or entering the program.

Staff noted if minimum operator volumes were set, the hospital license would be reviewed if one of the cardiologists did not meet the minimum requirement. Staff suggested thought needed to be given

to the process and how the regulatory component would be established. Staff requested that input regarding the regulatory process be submitted. Information submitted will be distributed to the committee.

With regard to how the hospital would track volumes of operators performing at different hospitals, Dr. Baute stated credentialing should be done by proxy with the main hospital responsible for ensuring the minimum volume per operator is maintained.

Mr. Flynn asked if the ACC is responsible for accrediting programs. Dr. Audett said it wasn't, stating the regulatory function is not part of their purview.

Discussion continued regarding the minimum operator volume and it was determined that the committee would hear from cardiologists to gain their perspective. It was determined a vote would be taken at the next meeting and interested parties would be informed of the issues to be voted.

The next meeting was set for 25 March 2008 at 1:00 PM.

The Chair noted the next topic to be addressed by the committee is open-heart surgery. Staff noted the main item to be reviewed is the minimum volume standard of 500. Staff noted three hospitals are currently operating below that number.

3. Adjournment

There being no further business the meeting was adjourned at 2:25 PM.

Respectfully submitted,

Loreen Angell